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Informed Consent

A Reappraisal of Patients' Reactions

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In response to the November 1972 ruling of the California Supreme Court requiring complete, detailed disclosure of risks for procedures and treatments, a survey was made of the reactions of one hundred patients to this decision. A fictional man was described with a clinical diagnosis of brain tumor, and then the procedure for cerebral angiography and all of that procedure's potential complications were described. The majority of the patients surveyed responded that this complete disclosure of risks helped them in making an intelligent decision about giving consent for the procedure. However, 50 percent of these patients would have withheld consent for the procedure on learning of the complications. Although physicians would have reacted differently, it is certainly the patients' right to make the choices they did.

THE ISSUE OF INFORMED CONSENT has been a source of heated and often acrimonious discussions by physicians and attorneys. However, aside from a recent study from the Cleveland Clinic, which will be discussed below, patients' views have received little attention. A recent decision by the California Supreme Court has forced the issue to the forefront again.

Physicians' views on the subject tend to be one of the following:

- The patient must be told everything about any complications that might ensue from a procedure or treatment.
- The patient must be told nothing because it is a waste of time. (The rationale for this position is that patient lacks the background to scientifically weigh the advantages and disadvantages of a medical decision.)
- Telling patients about threatening complications will cause undue anxiety which the patient can not handle.
- Detailed recitals of complications will result in patients' withholding of consent for procedures which their physicians feel are necessary.

Proponents of the last three views have argued that litigation over informed consent represents post hoc thinking, and that a complaint about inadequate information would never have been raised had the complication not occurred in the first place. They argue further that the informed consent concept is an expedient means of charging negligence when no negligence has occurred.

Attorneys have argued, on the other hand, and the current wave of consumerism in this country has supported them, that complete disclosure of advantages and disadvantages of any product or service is a basic right. There has been an implication on the part of the legal profession and plaintiffs that the physician who provides "inadequate" information about complications is trying

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to delude the patient. That this is rarely the case is, unfortunately, not generally appreciated outside the medical profession.

Dr. Ralph L. Alfidi provided a study of the patients' viewpoints of this topic.[1] His article reported the experience of the Cleveland Clinic with two separate studies. The first involved a detailed statement of the technique of angiography, followed by careful statements about thrombosis at the arterial puncture site and hematomas in the groin and more general statements about anaphylaxis and the possibility of stroke. The clinic's staff felt that this form was unnecessarily frightening to the patients; hence, a second form was adopted in which the complications were described in more general terms. The form was very favorably received by the patients. Eighty-nine percent of the patients felt that the form provided useful information. In response to this more general second form, 73 percent of the patients polled stated that they did not want more specific information about complications. Only 2 percent refused consent for the procedure on the basis of the complications mentioned on the form.

In November 1972, the California Supreme Court reviewed the issue of informed consent and issued rather sweeping changes in the consent laws as follows:

- With a complicated procedure the patient may choose to have a complete disclosure of complications or may choose to forgo such a disclosure.
- If he elects to have the complete disclosure, then he must be told about every foreseeable complication that is of serious medical consequence or that is potentially fatal.
- The patient no longer needs an expert witness to explain to the jury what the standard disclosure by the medical community would have been in a given case, but rather the jury can decide if the disclosure has been adequate.
- The proof that a patient-plaintiff would have refused a procedure if he had knowledge beforehand of such a complication would also be for the jury to assess. (In other words, the jury would be asked to decide, What would a prudent man do in similar circumstances?) Dr. David Rubsamen, an authority on Medico-legal affairs, concluded in his review of this case[2] that this verdict may well have a profound effect on future informed consent decisions all over the country.

Since we were concerned to see how patients as well as physicians would react to these changes, we began a study of patient responses to full disclosure of complications. As the situation was experimental, we elected not to begin our study with patients who were themselves going to have this procedure done, but rather sampled one hundred people who had no experience with the procedure at all.

Methods

One hundred patients ranging in age from 20 to 70, with an equal distribution of men and women, were given a printed questionnaire to be answered in the physician's office. Before they began their interviews, the patients were told that this was an experimental survey and that its purpose was to better understand patients' views on informed consent.

A fictional 55-year-old man was described whose only medical problems were headaches and left hemiparesis. On the basis of a full clinical examination and a brain scan, a provisional diagnosis of a mass lesion was made. The patients were told that the most definitive way to visualize the location, determine the probability of malignancy and the blood supply of the tumor (if tumor it was) was to obtain a cerebral arteriogram. They were also told that there was a possibility that the lesion was not a tumor, but that all indications were that it was. Also, if this were a tumor, the patient's symptoms would inevitably get worse and progress to a vegetative state and death. On the other hand, the study might demonstrate a potentially resectable lesion. They were then told that they would have to weigh this clinical state against the complications of the procedure. The overall complication rate for Kaiser Foundation Hospitals was given as 1.5 percent with an incidence of permanent neurologic sequelae of 0.5 percent. A detailed statement in lay language of the mechanics and technique of cerebral angiography was then given. Then all possible complications were listed and described in lay language, followed by a place for a yes or no response for each complication. The patients were asked to review the clinical situation of this fictional patient and the details of the procedure involved. They were then to decide, for each complication (putting themselves in this patient's shoes) if having knowledge beforehand of a given complication would cause them to withhold consent for the procedure. The complications as they were stated to the patients are listed in Exhibit 1, fol-

lowed by the responses to each question. Some general questions were then asked (listed in Exhibit 2) to assess the patients' general reactions to complete disclosure.

All the questionnaires were administered by one physician so that the explanation would be uniform. However, the patients had to answer all the questions by themselves. Any requests for the physician's opinion were denied. This was done to avoid any element of persuasion and also to avoid the variable of the individual physician's personality.

EXHIBIT 1.—*Patients' Attitude Toward Having Cerebral Arteriogram for Diagnosis and Location of Tumor*

Question	*Percent YES**	*Percent NO†*
1. You will have to lie perfectly still on a hard table for several hours during the procedure.	7	93
2. In rare instances, an allergy to the contrast medium might not be anticipated prior to the procedure. Hence, an allergic reaction might occur which would involve chills and welts over the skin. This might progress to shortness of breath. In extremely rare situations, an allergic reaction could be fatal.	14	86
3. In some patients the bleeding that naturally ensues when the artery is punctured may not be stopped totally. Under those circumstances, the blood may ooze out and form a large swelling in the groin called a hematoma. This eventually dissolves, but it can be very painful during the period of resolution which can be several days to a full week.	3	97
4. Some patients may have atherosclerosis in the large artery in the groin. Such patients rarely may form a clot in that artery at the end of the procedure. The presence of such a clot in the artery would make the leg cold and numb and painful. If such a clot develops, it has to be removed by a surgeon. This surgery is almost uniformly successful if done early. However, it is major surgery and it does involve general anesthesia.	7	93
5. The most important complications from arteriograms are due to strokes. A stroke means that a blood vessel in the brain has been blocked; hence, the brain tissue supplied by that blood vessel will become diseased and may be permanently injured. Most of these strokes are short-lived and clear up within one day. The incidence of permanent strokes is about 0.5 percent. Below are listed specific problems which can occur with strokes		
Complications		
(a) The arm on one side of the body might become very weak.	12	88
(b) The leg on one side of the body might become very weak.	13	87
(c) Both the arm and leg on one side of the body might be very weak.	16	84
(d) Sensation might be reduced or lost on one arm.	16	84
(e) Sensation might be reduced or lost on one leg.	19	81
(f) Sensation might be reduced or lost on one arm and leg.	19	81
(g) The ability to speak might be impaired. This might take the form of inability to say the word, inability to think of the word you wish to say, or inability to understand what is said to you.	32	68
(h) Double vision.	25	75
(i) You may be unable to see half or one quarter of your visual field.	26	74
(j) You may have abnormal sensations on your face which would make it feel asleep.	23	77
(k) You may have trouble chewing or swallowing.	23	77
(l) Decrease or loss of vision in one eye.	26	74
(m) In extremely rare situations, as a result of multiple strokes, you could come out of the procedure with decreased consciousness, unable to move or talk. You would have to be watched constantly by nurses and be nourished by vein.	28	72
(n) Rarely, you might die from the procedure.	24	76

*YES—Knowledge of this would cause me to refuse the procedure.
†NO—I would consent anyway.

EXHIBIT 2.—*Patients' Attitude Toward Detailed Discussion of Procedure and Risks*

	Percent YES	*Percent NO*
1. Do you feel that such a detailed discussion of risks helps you to make an intelligent decision for yourself about the procedure?	73	28
2. Conversely, does it hinder you in making such a decision because of disturbing worry?	27	73
3. Would you have preferred to have only been told about the procedure itself and not the complications?	24	76

Results

The percentages of patients who responded "yes" or "no" to our questions are given in Exhibits 1 and 2.

Our physician colleagues predicted that most patients would respond that a detailed discussion of risks would be of help to them; that it would not create so much disturbing worry as to hinder their thinking; and that they would not have preferred a consent method which only described the procedure and gave them no idea of the complications. As can be seen from the Exhibits, the prediction was born out in most cases. Fifty-four percent of those who disagreed indicated that none of the complications would have prevented them from giving consent for the procedure. That would seem to be a perfectly logical response for someone who in some way disapproved of a technique of complete disclosure. Nevertheless, there were 11 patients who stated that they did not feel that a detailed discussion of risks helped them in making an intelligent decision about having the procedure done, but they still would have withheld consent because of one complication or another. There were 17 who felt that disclosure caused them disturbing worry which hindered their making a decision, but who would have refused consent anyway because of complications. Ten patients who stated that they would have preferred to have only been told about the procedure itself and not the complications would have withheld consent for the procedure when they found out about complications.

Of the 100 patients surveyed, 50 would have withheld consent because of one complication or another. Of these, 30 limited their refusals of consent to knowledge of specific stroke syndromes. The remaining 20 did not so limit themselves.

Discussion

The majority of the patients polled responded as we had predicted. However, it should be noted that the percentages of those who disagreed, though in the minority, were not small. This would support the Supreme Court's contention that a full disclosure is not for everyone.

We were surprised to find that 50 percent of the patients polled would have withheld consent for a very important procedure because of knowledge of complications. This result is in glaring contrast to the result of Dr. Alfidi's study quoted above. The major differences between the two studies were: (1) that our patients were answering in the abstract, and his were actually having the studies themselves, and (2) our study included very specific statements about the conditions of patients who have strokes. It might be argued that if these individual complications were reviewed by an actual patient who knew that his personal physician had endorsed the cerebral arteriogram, he might feel more secure in taking the calculated risk in consenting to it. On the other hand, 60 percent of those who would have refused did so only because of specific, detailed knowledge of stroke syndromes, and the highest rates of refusal were for the most sinister complications. This would strengthen our conclusion that the very detailed description of the clinical picture of strokes had some influence on the high rate of refusals for consent in this study.

The spread of responses among the different types of strokes would indicate that there are some stroke syndromes to which some patients would object and others to which still other patients would object. Hence, it would appear that only a complete list of complications would satisfy everyone's needs. Furthermore, it has been my experience as a neurologist that it is unusual for a patient to have any concept of what the term *stroke* means. Hence, patients must be told more than "You may have a stroke." As might have been anticipated, the largest numbers of negative responses were in connection with the most threatening clinical states—aphasia, blindness, coma, and death. That such clinical states might emerge from the tumor itself did not seem to have swayed the patients' thinking.

Although the question was not asked, many patients volunteered that they found the kind of thinking required in this questionnaire to be very difficult and that they were totally unprepared for decision-making of the kind the study required. Perhaps in a few years when the public is more accustomed to thinking of this type, the results of such a study would be different. In the meantime, perhaps the spreading wave of consumerism will make patients aware of their rights and of their responsibilities for their own decisions.

In conclusion, the results of this study would certainly suggest that the Supreme Court's opinion is in accord with what the majority of our patients desire. The majority of patients felt that a complete, detailed discussion of risks did help them in making an intelligent decision about consenting to a procedure; that they were not hindered in making the decision because of the disturbing

worry that ensued; and that they wanted to know about the complications as well as about the procedure. The Supreme Court's ruling also makes it possible for those who do not want a full disclosure of risks to choose accordingly.

We were somewhat upset to find that 50 percent of the patients polled would have withheld consent for this procedure because they knew about complications. It can only be hoped that their refusals would be based on as thorough an *understanding* as possible of the relative prognosis of their disease versus the relative risks of the procedure.

Acknowledging the mitigating factors mentioned above, we are left with the conclusion that when patients are given a complete disclosure of risks, their choices about this procedure would be at variance with what their physicians would have predicted. The Supreme Court decision simply affirms that this variance is the patients' right and it must be respected.

It should be emphasized that the patients who participated in this study had never had neurological problems themselves in the past and were not themselves facing the prospect of angiograms in the future. The purpose of the study was to assess the reactions of patients in general to the experience of a complete disclosure of risks. Now that we have the preliminary experience of this study as background, we hope, in the future, to be able to collect a series of the reactions of actual patients to a complete disclosure of risks.

REFERENCES

1. Alfidi RJ: Informed Consent: A Study of Patient Reaction. JAMA 216:1324-1329, 1971
2. Rubsamen DS: Professional Liability Newsletter. 4:9, 1972